IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Oleg Iliich Epshtein
Title of Invention	:	A Medicinal agent and method for curing erectile dysfunction
Date Filed	:	January 22, 2005
Serial No.	:	10/522,650
Examiner	:	Ouspenskii, I.
Art Unit	:	1644
Confirmation No.	:	7546

DECLARATION UNDER 37 CFR 1.132

I, O. I. Epshtein, Dr. Sc, do hereby declare as follows:

1. My name is Dr. Oleg I. Epstein (aka Epshtein). I am a widely recognized scientist in the fields of pharmacology and physiology. I authored over 100 articles in the peer-reviewed journals.

2. The company I lead, Materia Medica Holdings, successfully sells the product covered by the above-identified application 10/522,650. I am the inventor of the '650 application.

3. Attached herewith as Exhibit I is a Report entitled *Sexual Behavior And Erectile Function In Mature Rats With Reduced Erectile Function: The Influence Of 4-week Treatment*, (2007) prepared by Institute of Psychology, University of Tromsoe, an outside vendor retained by Materia Medica to conduct an independent evaluation of the effectiveness of Materia Medica's preparation of homeopathic form of antibodies to NO synthase. The substance of the report is incorporated by reference herein and discussed below in brief.

4. The mice were divided into 5 Groups of 10. Group 1 (control group) was given oral administration of distilled water, administered in one dose: 3 ml/kg daily for 28 days. Mice in Groups 2 and 3 were given oral administration of antibodies to endothelial NO synthase, ultra-low doses (active ingredient of impaza) administered in two doses: 3 ml/kg and 9 ml/kg respectively daily for 28 days. Group 4 was given oral

administration of antibodies to endothelial NO synthase, ultra-low doses (active ingredient of impaza) and sildenafil citrate (Viagra) administered in one dose: 3 ml/kg of impaza and 3 mg/kg sildenafil citrate twice weekly for 28 days. On the days that sildenafil was not given, distilled water was administered. Group 5 was given sildenafil citrate administered in one dose: 3 mg/kg twice weekly. On the days that sildenafil was not given, distilled water was administered. Behavioral testing was performed on days 0 (baseline) and at treatment days 7, 14 and 28.

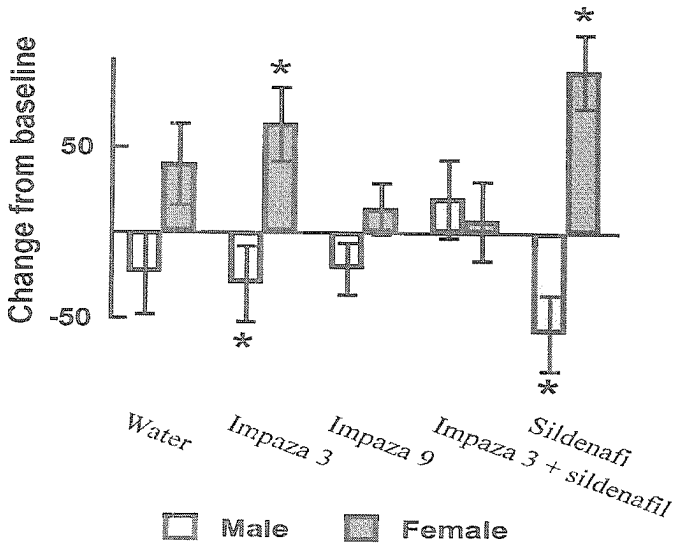
5. The following behavioral parameters were recorded: mount latency; intromission latency; ejaculation latency; post ejaculatory interval; number of mounts and number of intromissions. Sexual motivation was quantified in several ways. Most important for evaluating changes in the sexual incentive value of the receptive female are the preference score (time spent in the female incentive zone/(time spent in the female incentive zone + time spent in the male incentive zone)) and time spent in the female incentive zone. Table 1 below shows that in Fisher 344 rats treatment with sildenafil or Impaza, 9 ml/kg enhanced the intromission ratio at day 28 of treatment Table 2 below suggests that in Wistar rats Impaza 3ml/kg augmented the time present in the female incentive zone between baseline and the test on day 28 of treatment and reduced the time spent in the male incentive zone. Sildenafil had an identical effect. The other treatments were ineffective.

Table 1 - Copulatory behavior in Fisher 344 males at the test performed on day 28 of treatment. Data are mean ± SEM

Behaviour parameter	Treatment				
	Water	Impaza 3	Impaza 9	Impaza 3 + sildenafil	Sildenafil
Mount latency	164 ± 76	180 ± 87	55 ± 11	189 ± 136	258 ± 144
Intromission latency	141 ± 48	223 ± 88	66 ± 16	202 ± 138	246 ± 133
Ejaculation latency	339 ± 52	353 ± 51	416 ± 159	228 ± 95	316 ± 100
Postej. interval	350 ± 48	364 ± 41	315 ± 56	280 ± 14	306 ± 21
N of mounts	15 ± 5	10 ± 4	3 ± 1	9 ± 7	5 ± 3
N of intromissions	5 ± 1	8 ± 2	4 ± 2	2 ± 1	4 ± 1
Intromission ratio	0.25 ± 0.07	0.49 ± 0.06	0.66 ± 0.05*	0.46 ± 0.13	0.61 ± 0.13*

*, different from water, $P < 0.05$, Duncan's multiple range test.

Table 2 - Mean ± SEM change from baseline (in Wistar rats) in time (sec) spent in the male and female incentive zones at day 28 of treatment. * $P < 0.05$(observed value compared to 0 (no change) with a t-test).



6. Attached herewith as Exhibit II, is a Report entitled *Sexual Behavior And Erectile Function In Old Rats: The Influence Of 4-week Treatment*, (2006) prepared by Institute of Psychology, University of Tromsoe, an outside vendor retained by Materia Medica to conduct an independent evaluation of the effectiveness of Materia Medica's preparation of homeopathic form of antibodies to NO synthase. Also attached herewith as Exhibit III, is an article entitled *Sexual Incentive Motivation In Old Male Rats: The Effects Of Sildenafil And A Compound (Impaza) Stimulating Endothelia NO Synthase,* Pharmacology, Biochemistry and Behavior 89 (2008), 209-217. The substance of the report and the article are incorporated by reference herein and discussed below in brief.

7. The mice were divided into 5 Groups of 10. Groups 1 and 2 were given currently used sample (sample 1) containing antibodies to endothelial NO synthase, ultra-low doses (active ingredient of impaza) administered in two doses: 3 ml/kg and 9 ml/kg respectively daily for 28 days. Mice in Group 3 was given experimental sample (sample 2) containing antibodies to endothelial NO synthase, ultra-low doses (active ingredient of impaza) administered in one dose: 3 ml/kg daily for 28 days. Group 4 (control group) was given oral administration of distilled water, administered in one dose: 3 ml/kg daily

for 28 days. Group 5 was given sildenafil citrate administered in one dose: 3 mg/kg twice weekly. On the days that sildenafil was not given, distilled water was administered. Behavioral testing was performed on days 0 (baseline) and at treatment days 7, 14 and 28.

8. Table 3 shows that sample 1 administered in the volume of 3 ml/kg for 4 weeks stimulates sexual motivation in old, sexually inactive male rats. Table 4 shows that that there was a significant difference between the time spent in the receptive female incentive zone than in the male incentive zone only in the group treated with sample 1, 3 ml/kg or with sildenafil. In the other groups, there was no significant difference between the time spent in the vicinity of the male incentive and that spent in the vicinity of the female incentive.

Table 3- Mean ± SEM preference score in 5 groups of male rats at the test of day 28 of treatment. *, difference from no preference, a score of 0.5, P<0.05; +, difference from water, P<0/.05.

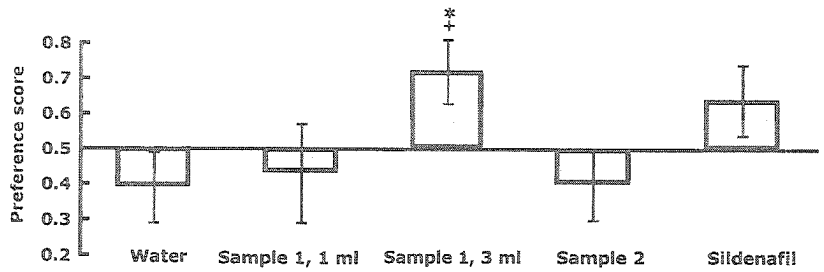
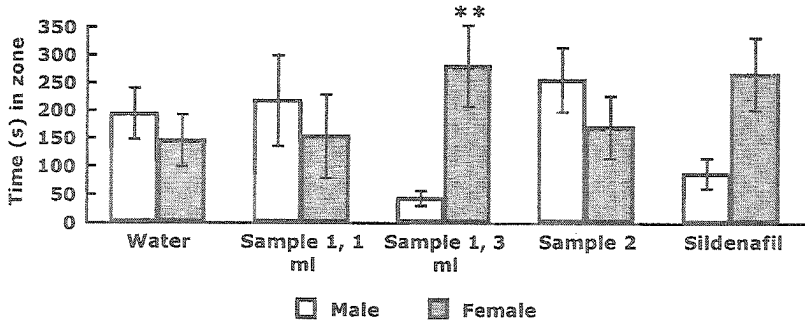


Table 4 – Time spent (sec) in the incentive zones at the test on treatment day 28.



9. The above described data suggest that treatment in Fisher 344 males with Impaza, 9 ml/kg facilitates vaginal penetration through enhanced erection as well as sildenafil; treatment in Wistar rats with 3 ml/kg or sildenafil increase sexual motivation as well as sildenafil; and old rats treated with Impaza 3 ml/kg displayed a preference for the sexually receptive female.

10. In my opinion, the results of the Institute for Psychology study clearly support a conclusion that a preparation based on homeopathic dilution of antibodies NO synthase is statistically far more effective than placebo (water).

11. It is also my opinion that a preparation based on homeopathic dilution of antibodies to NO synthase is at least as effective as or more effective than sildenafil.

12. It is also my opinion that the results of use of Impaza in rat model described in Exhibits I-III would be unexpected by one skilled in the field of erectile dysfunction. In particular, one skilled in the art could not expect, in my opinion, that Impaza will demonstrate results comparable to sildenafil, which is the standard of care for erectile dysfunction.

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

Dated: August 13, 2009

_____

_Dr. Oleg I. Epstein

Attorney Docket No. 841/006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Oleg Iliich Epshtein
Title of Invention	:	A Medicinal agent and method for curing erectile dysfunction
Date Filed	:	January 22, 2005
Serial No.	:	10/522,650
Examiner	:	Ouspenskii, I.
Art Unit	:	1644
Confirmation No.	:	7546

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION (RCE) AND AMENDMENT

Sir:

In response to the Final Office Action mailed on February 18, 2009, please enter the following amendments and reconsider the application in view of the RCE, these amendments and the following remarks.

Petition for Extension of Time begins on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims, which begins on page 3 of this paper.

Remarks/Arguments begin on page 5 of this paper.

PETITION FOR EXTENSION OF TIME

It is hereby petitioned that the period for response be extended by 3 month(s) pursuant to 37 CFR 1.136(a), so that it will expire on August 18, 2009

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A medicament for ~~effective in~~ treating ~~an~~ erectile dysfunction comprising a homeopathically potentised ~~one or more homeopathic dilutions of potentiated~~ form of monoclonal, polyclonal, or natural antibody~~ies~~ to an endothelial nitric oxide synthase (NO synthase)~~, wherein the potentiated form does not bind the NO synthase, one or more of the homeopathic dilutions of the potentiated form of antibodies to the NO synthase being obtained by a homeopathic potentiation technology~~.

2. (Currently Amended) The medicament according to claim 1, wherein the monoclonal, polyclonal, or natural antibody~~ies~~ is ~~are~~ prepared from an entire molecule ~~or from polypeptide fragments~~ of the ~~a~~ NO synthase enzyme.

3. (Withdrawn) A method of treating erectile dysfunctions and vegetative disturbances of male climax by regulating the level of cyclic guanosine monophosphate (cGMP) in the cavernous bodies on sexual stimulation characterized by the use of activated forms of ultra-low doses of antibodies to the entire molecule of endothelial NO synthase or to its polypeptide fragments, the activated forms being prepared by multiple consecutive dilutions and exposure to external factors.

4. (Withdrawn) A method of treating according to Claim 3 characterized by using mixtures of various, mostly centimal, homeopathic dilutions of antibodies to the entire molecule of the endothelial NO synthase or to its polypeptide fragments.

5. (Currently Amended) The medicament according to claim 9 ~~1~~, wherein said one or more of the homeopathic dilutions comprises one or more centesimal homeopathic dilutions.

6. (Currently Amended) A medicament for ~~effective in~~ treating ~~an~~ erectile dysfunction comprising **homeopathically potentised** ~~one or more homeopathic dilutions of potentiated~~ form of monoclonal, polyclonal, or natural antibody~~ies~~ to a ~~**synthetic polypeptide corresponding to a**~~ fragment ~~**1185-1205**~~ of ~~**an animoacid sequence of an endothelial Type III**~~ nitric oxide synthase (NO synthase), **having SEQ ID NO:1** ~~wherein one or more of the homeopathic dilutions of the potentiated antibodies to the NO synthase being obtained by a homeopathic potentiation technology~~.

7. (Currently Amended) The medicament according to claim 10 ~~6~~, wherein said one or more of the homeopathic dilutions comprises one or more centesimal homeopathic dilutions.

8. (New) The medicament according to claim 1, wherein the monoclonal, polyclonal, or natural antibody is prepared from a polypeptide fragments of the NO synthase enzyme.

9. (New) The medicament of claim 1, wherein said homeopathically potentised form comprises one or more homeopathic dilution.

10. (New) The medicament of claim 6, wherein said homeopathically potentised form comprises one or more homeopathic dilution.

REMARKS

Claims 1-7 are pending. Claims 3 and 4 have been withdrawn from consideration.

In the Office Action mailed February 18, 2009, claims 1, 2 and 5-7 have been rejected as allegedly obvious under 35 U.S.C. § 103 over U.S. Patent No. 6,150,500 to Salerno ("*Salerno*") in view of *Davenas* et al., *Epshtein* et al., and *Feldman* et al. (of record). Newly presented Claims 6-7 were joined to the rejection of record. Claims 1, 2 and 5 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by *Davenas* et al. and *Epshtein* et al. Claims 1, 2 and 5-7 were rejected under 35 U.S.C. § 112 as indefinite.

By this Amendment, Applicants amended claims 1, 2, 5-7 and added new claims 8-10. Support for new claims 8-10 may be found in the specification and claims as filed. No new matter has been added. Applicants respectfully request reconsideration and allowance of all pending claims in view of the amendments and remarks set forth below.

I. AMENDED CLAIM 1 IS SUPPORTED IN THE APPLICATION AS FILED

As amended, claim 1 now recites:

> 1. (Currently Amended) A medicament for treating erectile dysfunction comprising a homeopathically potentised form of monoclonal, polyclonal, or natural antibody to an endothelial nitric oxide synthase (NO synthase).

Applicants are fully aware that the newly added limitation "homeopathically potentised" is not set forth in the application in *ipsis verbis*. For this reason and to advance the prosecution on the merits, Applicants wish to address the issue preemptively and directly for Examiner's consideration.

Applicants note that *haec verbis* disclosure is not a pre-requisite for complying with the written description requirement. *See* MPEP § 2163. I. B. The description may be express, implicit, or inherent. *Id.* The key to evaluating compliance with the written description requirement is a determination whether the applicant had possession of the claimed invention based on the content of the application as a whole. *See* MPEP § 2163. II. The outcome of the evaluation depends on

whether "the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed." *See* MPEP § 2163.01, *citing In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

The specification describes: a) preparation of "potentiated" or "activated" antibodies to NO synthase by homeopathic technology (*e.g.*, page 2, paragraphs 5-6), b) administration of the activated or potentiated form of the NO synthase antibody to patients (*e.g.*, Example 3), and c) biological effects of such administration (*e.g.*, Example 3). In combination, these disclosures clearly place "homeopathically activated form" of the antibodies in possession of the inventors as of the filing date of the above-identified application.

Therefore, Applicants respectfully submit that amended claims 1, 2 and 5-7 and new claims 8-10 are fully supported in the application as filed.

II. OBVIOUSNESS REJECTION OVER *SALERNO* IN VIEW OF *DAVENAS ET AL., EPSHTEIN,* ET AL. AND *FELDMAN ET AL.*

The Examiner has rejected claims 1, 2 and 5-7 as allegedly obvious over *Salerno* in view of *Davenas* et al., *Epshtein,* et al. and *Feldman* et al. In the Office Action, the Examiner appears to suggest that one skilled in the art would be motivated to combine *Salerno* with *Davenas* et al. and/or *Epshtein* et al. based on the motivation of *Feldman*, et al. - *i.e.*, use the antibodies to NO synthase as disclosed by *Salerno* in the manner disclosed in *Epshtein* et al. and/or *Davenas* et al. to arrive at the medicament of the present invention. The Examiner also suggests that one skilled in the art would have a reasonable expectation that such combination/modification would be successful.

Applicants strongly and respectfully disagree. As amended claims 1, 2 and 5-7 and new claims 8-10 are directed to homeopathically potentised form of antibodies to an endothelial nitric oxide synthase (NO synthase).

Salermo discloses antibodies to NO synthase at normal concentration. Davenas et al. teach

that degranulation of basophils contained in leukocyte suspensions was induced by diluted anti-IgE antibody. *Feldman* et al. disclose the treatment of rheumatoid arthritis with anti-TNF antibodies in conjunction with anti-CD4 antibody and disclose that a benefit of combination treatment is that lower dosages can be used which outcome is economically advantageous. *Epshtein* et al. disclose an effect of ultra-low doses of antibodies to brain-specific antigen (S-100) on behavior characteristics in rat. *Epshtein* et al. report that administration of the antibody led to changes in rat behavior for a partial group of rats in the study (for example, an increase in the latent period of the emotional reflex reaction).

To set forth a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have a reasonable expectation that the combination of *Salerno* and *Epshtein/Davenas* will be successful. *See* § MPEP 2143.02. Meeting the burden requires that the prior art provides some degree of predictability. *Id.*, *citing In re Rhinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). In the pharmaceutical arts, the expectation of success is reasonable when the prior art as a whole would lead one skilled in the art to believe that the claimed invention would at least have activity of some type for the stated purpose. *In re O'Farrell*, 853 F.2d 984, 903 (Fed. Cir. 1988), *In re Merck*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The Court of Appeals for the Federal Circuit suggested that finding of reasonable expectation of success for a pharmaceutical product requires an expectation of activity greater than a baseline level of activity. *Yamanouchi Pharmaceutical, Inc. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1345 (Fed. Cir. 2000).

Applicants respectfully submit that none of the references, alone or in combination, disclose, teach or suggest anything that would lead one skilled in the art to expect that a homeopathically activated form of an antibody to NO synthase would have any activity, let alone the specific activity levels observed. *Epshtein* et al. does disclose that an activated form of an antibody to brain-specific antigen has some effect on rat behavior. How does this lead one skilled in the art to expect any activity of homeopathically activated antibodies to NO synthase, let alone the specific activity observed? None of the references, including Salerno, *Epshtein* et al. or *Davenas* et al., disclose a mechanism of action for the potentiated antibodies, *or contain any other information that would suggest to an artisan that what works for one type of antibodies would work for another.* While Applicants are well aware of the decision of the United States Supreme

Court in *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727 (2007), the facts of the present case have nothing to do with a situation where "there are a finite number of identified, predictable solutions," when "a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp." *KSR Int'l* at 1742. As it is well-known to those skilled in the art, the universe of various antigen-antibody pairs is nearly limitless.

Furthermore, to set forth a *prima facie* case of obviousness, the Examiner must show that the prior art taken in its entirety provides a reason for one skilled in the art to arrive at the invention as a whole. MPEP § 2141.02. It is improper to focus on the specific difference between the prior art and the invention as such. *Id.* The question is whether the prior art in its entirety provides "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l* at 1742. Considering the invention as a whole, the entirety of the prior art did not provide such "apparent reason." The Examiner pointed to *Feldman*'s teaching that lower doses of antibodies would "offer the advantage of lower financial costs to the patient," and asserted that this *Feldman* statement would provide a motivation to one skilled in the art to move in the direction of the claimed invention. As the specification of the present application makes explicitly clear, the claimed medicament contains "homeopathically activated form" of an antibody. The difference between the "homeopathically activated form" and the form of *Feldman* is not simply quantitative (as the Examiner appears to suggest). The difference is qualitative. At most, *Feldman* suggests a reduction in the traditional dose is a benefit of combination therapy. How such reduction provides "an apparent reason" to cross the barrier from traditional doses to the qualitatively and intrinsically different form claimed in the amended claim 1?

Applicants submit hereby a Declaration by Dr. Oleg Epshtein ("the *Epshtein Declaration I*"). The *Epshtein Declaration I* is submitted as evidence in further response to Examiner's allegations of *prima facie* obviousness. The *Epshtein Declaration I* is submitted to show absence of *prima facie* obviousness, not in rebuttal of the alleged *prima facie* case. In the *Epshtein Declaration I*, Dr. Epshtein states that one skilled in the art would not expect that a homeopathically activated form of an antibodies to NO synthase would be active for intended purpose based on the information provided in the prior art at the time the '650 application was filed. Applicants respectfully assert that the *Epshtein Declaration I* is un-rebutted evidence of

non-obviousness, and it provides further support for non-obviousness of amended claims 1, 2, 5-7 and new claims 8-10.

Applicants respectfully suggest the Examiner did not put forth a *prima facie* case of obviousness with respect to claims 1 and 6, as amended and dependent claims.

While Applicants believe that the evidence in the file wrapper does not support *prima facie* obviousness of amended claims 1, 2, 5-7, Applicants wish to submit rebuttal evidence to advance the prosecution on the merits. Attached herewith is another Declaration by Dr. Epshtein ("the *Epshtein Declaration II*") that includes evidence that the claimed invention yields unexpected properties and that the medicament of the present invention based on homeopathic dilution of antibodies to NO synthase is statistically far more effective than placebo (water). Furthermore, while not necessary to establish patentability, the study also demonstrated that the homeopathically activated form of antibodies to NO synthase is at least as effective as or more effective than sildenafil, a well-known and accepted pharmaceutical compound used in treating erectile disfunction. For example, the difference in intromission rate between subjects treated with the homeopathic dilution of antibodies to NO synthase, sildenafil and the control subjects is undoubtedly statistically significant ($p<0.05$) and cannot be ascribed to anything other than the unexpected and superior activity of the claimed preparation. Applicants respectfully assert that the *Epshtein Declaration II* is un-rebutted evidence of non-obviousness, and it provides further support for non-obviousness of claims 1, 2 and 5-7. Would one skilled in the art expect the magnitude and nature of effect described? Epshtein Declarations I & II which are the evidence now in the file, clearly established that the answer is in the negative.

Applicants respectfully submit that none of the references, alone or in combination, disclose, teach or suggest anything that would lead one skilled in the art to expect that a homeopathically activated form of an antibody to NO synthase would have any activity, let alone the specific activity levels reported in the *Epshtein Declaration II*.

On the basis of the foregoing, Applicants respectfully submit that claims 1 and 6, as amended and dependent claims are non-obvious. Withdrawal of the rejection is respectfully requested.

III. REJECTION OF NEWLY PRESENTED CLAIMS 6 AND 7

Claims 6 and 7 were joined to the rejection of record in that claim 6 recites that the antibody corresponds to a fragment, which language is interpreted to be an open sequence language. The Examiner also indicated that claim 6 contains the indefinite article "a" rather than the definite article "the" in reference to the peptide sequence.

Claim 6 has been amended to eliminate the indefinite article "a" and to identify the exact sequence of the fragment. Thus, Claim 6 as amended recites a medicament for treating erectile dysfunction comprising homeopathically potentised form of monoclonal, polyclonal, or natural antibody to a fragment of nitric oxide synthase (NO synthase), having SEQ ID NO:1.

Applicants respectfully submit that claim 6 as amended and dependent claim 7 are non-obvious. Withdrawal of the rejection is respectfully requested.

IV. ANTICIPATION REJECTIONS OVER DAVENAS ET AL. AND EPSHTEIN ET AL.

The Examiner has rejected claims 1, 2 and 5 as allegedly anticipated by Davenas et al. and Epshtein et al. As amended claim 1 recites:

> 1. A medicament for treating erectile dysfunction comprising a homeopathically potentised form of monoclonal, polyclonal, or natural antibody to an endothelial nitric oxide synthase (NO synthase).

To anticipate a claim, a reference must disclose, either explicitly or inherently, each element of the claim. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The prior art cited by the Examiner does not disclose each and every element of rejected claim 1, either explicitly or inherently.

Nothing in *Davenas et al.* teaches anything related to homeopathy, let alone to "homeopathically activated form of antibodies to NOS." Withdrawal of the anticipation rejection is respectfully requested.

Epshtein et al. discloses an effect of ultra-low doses of antibodies to brain-specific antigen (S-100) on behavior characteristics in rat. *Epshtein et al.* does not teach anything homeopathically activated form of antibodies to NOS. Withdrawal of the anticipation rejection is respectfully requested.

V. INDEFINITENESS REJECTION OF CLAIMS 1, 2 AND 5-7

The Examiner rejected claims 1, 2 and 5-7 as indefinite in that the claims recite "potentiated antibodies to NO synthase" and then proceed to recite that the potentiated antibodies do not bind NO synthase. The Examiner further states that there are numerous NO synthases and reciting a fragment by its position within a larger amino acid sequence without identifying the exact sequence renders the claim uncertain.

As amended claim 1 does not recite that the antibodies do not bind NO synthase. Claims 6 has been amended to recite antibody to a fragment of nitric oxide synthase (NO synthase), having SEQ ID NO:1. As such, it is clear that the exact sequence of the fragment is clearly identified.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No.11-0223

Respectfully submitted,

Dated: August 13, 2009

By:/Edward D. Pergmanet/
Edward D. Pergament
(Reg. No. 43,346)
Attorney for Applicant(s)

K:\Clients\Epshtein, Oleg Dr. -841\841-006\841-006_Amendment.doc